Addenda
FDA Briefing Package

Division of Pulmonary and Allergy Products
Office of New Drugs
Office of Drug Evaluation II

Office of Surveillance & Epidemiology

Joint Meeting of the Pulmonary-Allergy Drugs Advisory Committee and Drug Safety and Risk Management Committee
March 10-11, 2010

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	February 16, 2010
To:	Lydia Gilbert-McClain, MD, FCCP Deputy Director Division of Pulmonary and Allergy Products Office of New Drugs
Through:	Solomon Iyasu, M.D., MPH Director Division of Epidemiology Office of Surveillance and Epidemiology Laura Governale, Pharm.D., MBA Drug Use Data Analyst Team Leader Division of Epidemiology Office of Surveillance and Epidemiology
From:	Grace Chai, Pharm.D. Drug Use Data Analyst Division of Epidemiology Office of Surveillance and Epidemiology
Subject:	Long Acting Beta Agonists (LABA) Drug Utilization Review
Drug Name(s):	Advair products (fluticasone/salmeterol), Symbicort (budesonide/formoterol), Serevent products (salmeterol), Foradil (formoterol), inhaled corticosteroids
Application Type/Number:	multiple
Applicant/sponsor:	multiple
OSE RCM #:	2010-207

EXECUTIVE SUMMARY

Utilization data for long acting beta agonists (LABAs), salmeterol and formoterol, were requested by the Division of Pulmonary & Allergy Products in support of the FDA's Pulmonary-Allergy Drug Products Advisory Committee meeting to be held on March 10-11, 2010 to discuss the design of a study to evaluate the safety of LABA-containing products when added to inhaled corticosteroids (ICS) compared to ICS alone in patients with asthma. This analysis is focused on use of LABA-containing products but includes inhaled corticosteroid use, by patient ages (pediatric: 0-11 years and adolescent/adult: 12+ years old) for the eight year period from year 2002 to year 2009.

Results from year 2002 to year 2009, with a focus on year 2009:

- The total number of LABA-containing prescriptions increased from ~15.6 million prescriptions to ~21.7 million prescriptions from year 2002 to 2009, accounting for ~17% of the asthma market in year 2009. In year 2009, over 95% of LABA-containing products were dispensed as combination LABA products, salmeterol/fluticasone and budesonide/fluticasone. Dispensed prescriptions for combination LABA products increased while prescriptions for single-agent LABA products decreased from year 2002 to 2009.
- There were ~873,000 prescriptions (~4% of LABA market) dispensed for LABA-containing products to the pediatric population (ages 0-11 yrs) in year 2009.
- Salmeterol/fluticasone prescriptions were the third most frequently dispensed asthma medication and the top LABA-containing product dispensed with ~18.1 million prescriptions (~14% of asthma market) for the overall population.
- There were ~532,000 single-agent salmeterol prescriptions dispensed to the overall population (~0.4% of asthma market) in year 2009, a decrease from ~5 million prescriptions (~4.7% of asthma market) in year 2002.
- Salmeterol/fluticasone was the sixth most frequently dispensed asthma medication in the pediatric population with ~740,000 prescriptions (~3.3% of pediatric asthma market) during year 2009, a decrease from ~780,000 prescriptions (~4.0% of pediatric asthma market) in year 2002.
- Salmeterol/fluticasone use in the 12 years and older population increased sharply from ~9.4 million prescriptions in year 2002, to ~17 million prescription in year 2006 and remained roughly at that level through year 2009,
- The total number of unique patients who received a prescription for a LABA-containing product increased from ~4.9 million patients to ~6.2 million patients from year 2002 to 2009. The number of pediatric patients decreased from ~409,000 patients (~8.3% of patients receiving a LABA-containing product) to ~322,000 patients (~5.2% of patients receiving a LABA-containing product) during the same time period. Patient trends reflected dispensed prescription trends.
- "General Practice/Family Medicine" was the top prescribing specialty for salmeterol and formoterol products in the total population.
- "Asthma NOS" was the top diagnosis associated with the use of LABA-containing products for both populations, though ~22% of drug use mentions for LABA-containing products in the 12+ year population were for "COPD".
- From year 2002 to 2009, the number of dispensed ICS prescriptions in the pediatric population increased from ~3.9 million prescriptions (16.5% of the total ICS market) to ~5.2 million prescriptions (16.1% of the total ICS market). Single agent budesonide was the top ICS product in the pediatric market. Salmeterol/fluticasone combination products were the top ICS containing products in the 12+ years ICS market. Fluticasone was the most frequently dispensed single-agent ICS in both populations.

1 INTRODUCTION

The Division of Pulmonary and Allergy Products is conducting an Advisory Committee on March 10-11, 2010 to discuss the design of a safety study to determine the safety of two long acting beta-agonists (LABAs), salmeterol and formoterol, when added to inhaled corticosteroids (ICS) compared to ICS alone in patients with asthma. The Division of Epidemiology, in support of this review, has been requested to provide utilization data for LABA-containing products and ICS products in the pediatric (0-11 years old) and adolescent and adult population (12+ years) from year 2002 to 2009.

2 METHODS AND MATERIAL

2.1 DETERMINING SETTINGS OF CARE AND DATA SOURCES USED

We examined the wholesale distribution data for salmeterol- and formoterol-containing products, two LABAs, for year 2009 to determine the distribution pattern for these products. Overall, salmeterol and formoterol-containing products were distributed mainly to outpatient retail pharmacy channels at ~55% of the market share. Mail service was second in market share at ~30%, followed by non-retail pharmacy channels at ~15% during year 2009.[1] Thus, outpatient retail pharmacy settings, excluding mail order, were assessed to provide utilization patterns. Outpatient retail pharmacy settings include chain, independent, food stores with pharmacies.

2.2 DATA SOURCES USED

Proprietary drug use databases licensed by the Agency were used to conduct this analysis. The estimated number of prescriptions dispensed and unique patients for LABA-containing products was obtained from the SDI, Vector One®: National (VONA) and SDI, Vector One®: Total Patient Tracker (TPT) databases for years 2002 to 2009. Diagnoses, as mentioned by office-based physician practices around the country, were obtained from the SDI, Physician's Drug and Diagnosis Audit (PDDA) (see ***Appendix 1*** for full database descriptions).

3 DATA

3.1 LABA-CONTAINING PRODUCTS: SALMETEROL- OR FORMOTEROL-CONTAINING PRESCRIPTIONS IN THE ASTHMA MARKET

ALL AGES

Table 1 and Figure 1 in Appendix 2 show the top asthma prescriptions dispensed from U.S. outpatient retail pharmacies from years 2002 to 2009. The total dispensed prescriptions in the asthma market increased from ~107 million prescriptions to ~129 million prescriptions from year 2002 to 2009. Salmeterol/fluticasone products consistently remained the third most frequently dispensed medication in the asthma market, increasing in market share from ~9.5% (~10.2 million prescriptions of ~107 million asthma prescriptions) in year 2002 to ~14% (~18.1 million prescription s of ~129 million asthma prescriptions) of the asthma market in year 2009. Dispensed prescriptions for salmeterol/fluticasone increased from year 2002 to 2006 before stabilizing in growth. The second most frequently dispensed LABA-containing product in the asthma market were single-agent salmeterol products which accounted for ~1.6% of the asthma market (~15 million prescriptions of~948 million total asthma prescriptions) for the combined entire length of the examined time period. However, single agent salmeterol prescriptions decreased from ~4.7% (~5 million prescriptions of ~107 million asthma prescriptions) of the market share in year 2002 to ~0.4% (~532,000 prescriptions of ~129 million asthma prescriptions) of the market share in year 2009.

PEDIATRIC AGES 0-11 YEARS

Table 2 in Appendix 2 shows the number of dispensed asthma market prescriptions by patient age. The pediatric population (ages 0-11 yrs) accounted for ~18% of the total asthma market in year 2009 and for the

[1] IMS Health, IMS National Sales Perspectives™, Years 2002- 2009, Extracted 02/2010. File: 1002lab1.xls

entire combined study period. Figure 2 in Appendix 2 shows the top asthma medications dispensed for the pediatric population (0-11 years old) from U.S. outpatient retail pharmacies. In the pediatric population, salmeterol/fluticasone products were the sixth most frequently dispensed asthma product at ~3.3% (~741,000 prescriptions of ~22.7 million pediatric asthma prescriptions) of the pediatric asthma market in year 2009. (Appendix 2: Figure 2)

3.2 LABA-CONTAINING PRODUCTS: DISPENSED PRESCRIPTIONS FOR SALMETEROL OR FORMOTEROL CONTAINING PRODUCTS

ALL AGES

Table 3 in Appendix 2 shows the total number of dispensed prescriptions for salmeterol- and formoterol-containing products (LABAs) from U.S. retail pharmacies stratified by patient age (0-11 and 12+ years), molecule, product and strength in for years 2002 to 2009. The total LABA market increased from ~15.6 million prescriptions to ~21.7 million dispensed prescriptions from year 2002 to 2009. The LABA market accounted for ~17% (~21.7 million LABA prescriptions of ~129 million asthma prescriptions) of the asthma market in year 2009.

PATIENT AGE GROUP: PEDIATRIC AGES 0-11 YEARS

LABA prescriptions dispensed to the pediatric population accounted for ~4% (~873,000 prescriptions of ~21.7 million LABA prescriptions) of the total LABA market in year 2009. Salmeterol/fluticasone products were the most frequently dispensed LABA product accounting for ~85% of the pediatric (0-11 year old) LABA market (~740,000 prescriptions of 873,000 pediatric LABA prescriptions) in year 2009. Although there was an increase in the use of salmeterol/fluticasone beginning in year 2002, use actually decreased down from ~780,000 prescriptions in year 2002 to ~740,000 prescriptions in year 2009 in the pediatric population. Single-agent salmeterol and single-agent formoterol product use has decreased over the examined time in the pediatric population

PATIENT AGE GROUP: 12 YEARS AND OLDER

Salmeterol/fluticasone products were the most frequently dispensed LABA-containing product, accounting for ~83% in the adult (12+ years) population (~17.3 million prescriptions of ~20.8 million adult LABA prescriptions) in year 2009. Prescriptions dispensed to patients aged 12 years old and older increased from ~9.4 million prescriptions to ~17.3 million prescriptions over the study period, with the greatest increase seen from year 2002 to 2006. Proportionally, single-agent salmeterol and single-agent formoterol use has decreased over the examined time though the actual number of formoterol prescriptions increased slightly from year 2002 to 2009.

3.3 LABA-CONTAINING PRODUCTS: UNIQUE PATIENTS FOR SALMETEROL OR FORMOTEROL PRODUCTS

There was a cumulative total of ~23.2 million unique patients who received a prescription for a LABA-containing product from outpatient retail pharmacies during years 2002 to 2009. The number of unique patients on LABA-containing products increased from ~4.9 million patients to ~6.2 million patients from year 2002 to 2009. The pediatric population accounted for ~5.2% (~322,000 patients) of the patients receiving a LABA-containing product in year 2009, a decrease from ~8.3% (~409,000 patients) in year 2002. The greatest number of patients received salmeterol/fluticasone products in both patient age groups. Patient data trends reflected the dispensed prescription trends (Table 4: Appendix 2).

3.4 LABA-CONTAINING PRODUCTS DISPENSED PRESCRIPTIONS BY PRESCRIBING SPECIALTY

Table 5 in Appendix 2 shows the top prescribing specialties for LABA-containing products by number of dispensed prescriptions. "General Practice/Family Medicine" was the top prescribing specialties in the total population with ~30% of all prescriptions dispensed during the cumulative review period for years 2002 to 2009. "Internal Medicine" was second with ~23% of all dispensed prescriptions. The "Pediatrics" specialty accounted for ~7% of all dispensed prescriptions over the entire cumulative review period.

3.5 LABA-CONTAINING PRODUCT USE RELATED DIAGNOSIS

Table 6 in Appendix 2 shows the most common diagnoses associated with LABA-containing product use as reported by a survey of office-based physician practices around the United States by 4 digit ICD-9 codes. For the cumulative years 2002 to 2009, the top diagnosis code was "Asthma NOS" (ICD-9 493.9) for both pediatric patients aged 0-11 years old (~80% of drug use mentions) and patients aged 12 years and greater (~56% of drug use mentions). Approximately 22% of the LABA-containing product drug use mentions for patients aged 12 years and greater was for the diagnosis "Chronic Airway Obstruct NEC" (ICD-9 496.0) or COPD.

3.6 INHALED CORTICOSTEROID PRODUCTS DISPENSED PRESCRIPTIONS

Table 7a and 7b in Appendix 2 shows the total number of inhaled corticosteroid (ICS) prescriptions dispensed from U.S. outpatient retail pharmacies from years 2002 to 2009, stratified by patient age (0-11 and 12+ years), molecule, product and strength. ICS prescriptions dispensed to pediatric patients 0-11 years old accounted for ~17% (~37.5 million prescriptions of ~224 million ICS prescriptions) of the total ICS market for the cumulative time period. From year 2002 to 2009, the number of dispensed ICS prescriptions in this population increased from ~3.9 million prescriptions to ~5.2 million prescriptions. Single-agent budesonide products were the most frequently dispensed ICS product from years 2002 to 2009, accounting for a cumulative total of ~43% of the pediatric (0-11 year old) ICS market (~16.3 million prescriptions of ~37.5 million pediatric ICS prescriptions). During year 2009, single-agent budesonide products accounted for ~41% (~2.1 million prescriptions of ~5.2 million ICS prescriptions) of the ICS market in this population.

In the age 12+ year old population, salmeterol/fluticasone products were the most frequently dispensed prescription among the ICS containing products, accounting for a cumulative total of ~66% of the 12+ years ICS market (~123 million prescriptions of ~185 million ICS prescriptions). During year 2009, salmeterol/fluticasone products accounted for ~64% (~17.3 million prescriptions of ~27 million ICS prescriptions) of the ICS market in this population.

Single-agent ICS fluticasone products were the second most frequently dispensed product for both populations, accounting for a cumulative total of ~11.1 million prescriptions (30%) for the pediatric ICS market and ~30.2 million prescriptions (16%) for the 12+ year old ICS market during years 2002 to 2009. During year 2009, single-agent ICS fluticasone products accounted for ~1.6 million prescriptions dispensed (31%) for the pediatric ICS market and ~3.1 million prescriptions dispensed (12%) for the 12+ year old ICS market.

4 DISCUSSION AND LIMITATIONS

LABA-containing product use has increased along with the total asthma market during the examined time period. Use of salmeterol/fluticasone products increased sharply from year 2002 before stabilizing in growth in year 2006, though it consistently remained among the top three asthma medications in the total population. In the pediatric population, salmeterol/fluticasone use also increased from year 2002 to year 2005 but decreased starting in year 2006. Albuterol, montelukast, and single agent inhaled corticosteroids were more frequently dispensed in the pediatric population.

Total single-agent salmeterol use has also decreased since year 2002 in both patient populations. In a poster presented by Kaplan et.al, it was found that about half (~48%) of the patients in the studied population used salmeterol without concurrent use of an ICS, and ~30% of those patients, had no concurrent ICS use for greater than 31 days.[2] Although, single-agent salmeterol use has decreased since year 2002 for both populations, these findings suggest current LABA-containing product label recommendations and NAEPP Guidelines were not followed in this small proportion of asthmatic patients.

[2] Kaplan S, Ding Y, Mosholder A. Drug Concurrency Patterns among Asthma Patients Using Single-Ingredient LABA: A claims Data Study. Presented at "2009 International Society for Pharmacoepidemiology's 25th International Conference on Pharmacoepidemiology & Therapeutic Risk Management", Providence, Rhode Island.

Findings from this consult should be interpreted in the context of the known limitations of the databases used. We estimated that salmeterol and formoterol products are distributed primarily in outpatient retail settings based on the IMS Health, IMS National Sales Perspectives™. These data do not provide a direct estimate of use but do provide a national estimate of units sold from the manufacturer into the various channels of distribution. The amount of product purchased by these retail and non-retail channels of distribution may be a possible surrogate for use, if we assume the facilities purchase drugs in quantities reflective of actual patient use. This review focuses primarily on the outpatient retail pharmacy market which captures ~55% of the total LABA-containing product market. Mail order and inpatient settings data, representing ~45% of the LABA-containing product market was not included in this review.

Indications for use were obtained using SDI's PDDA, a monthly survey of 3,200 office based physicians. Although PDDA data are helpful to understand how drug products are prescribed by physicians, the small sample size and the relatively low usage of these products limits the ability to identify trends in the data. In general, PDDA data are best used to identify the typical uses for the products in clinical practice, and the VONA outpatient prescription data to evaluate trends over time.

SDI uses the term "drug uses" to refer to mentions of a drug in association with a diagnosis during an office-based patient visit. This term may be duplicated by the number of diagnosis for which the drug is mentioned. It is important to note that a "drug use" does not necessarily result in prescription being generated. Rather, the term indicates that a given drug was mentioned during an office visit.

5 CONCLUSIONS

Total LABA-containing product use has increased since year 2002, along with the increase in the total asthma market. Within the asthma market, LABA-containing products were used less frequently in the pediatric population compared to the 12+ year old population for asthma. Salmeterol/fluticasone products has consistently ranked third among the top asthma medications in the overall population. A sharp increase in use was observed from year 2002 to year 2006, then stabilized in the 12+ year old population; however, there was a slight decline in use in the pediatric population. Albuterol, montelukast, and budesonide products were more frequently dispensed over the LABA-containing products in the pediatric population. Despite the decrease in use of the single-agent LABA-containing products, Kaplan et.al., found that nearly half of the patients studied used salmeterol without concurrent use of an ICS. These findings suggest current LABA-containing product label recommendations and NAEPP Guidelines are not followed in this small proportion of asthmatic patients.

APPENDIX 1: DATABASE DESCRIPTIONS

IMS Health, IMS National Sales Perspectives™: Retail and Non-Retail

The IMS Health, IMS National Sales Perspectives™ measures the volume of drug products, both prescription and over-the-counter, and selected diagnostic products moving from manufacturers into various outlets within the retail and non-retail markets. Volume is expressed in terms of sales dollars, eaches, extended units, and share of market. These data are based on national projections. Outlets within the retail market include the following pharmacy settings: chain drug stores, independent drug stores, mass merchandisers, food stores, and mail service. Outlets within the non-retail market include clinics, non-federal hospitals, federal facilities, HMOs, long-term care facilities, home health care, and other miscellaneous settings.

SDI Vector One®: National (VONA)

SDI's VONA measures retail dispensing of prescriptions or the frequency with which drugs move out of retail pharmacies into the hands of consumers via formal prescriptions. Information on the physician specialty, the patient's age and gender, and estimates for the numbers of patients that are continuing or new to therapy are available.

The Vector One® database integrates prescription activity from a variety of sources including national retail chains, mass merchandisers, mail order pharmacies, pharmacy benefits managers and their data systems, and provider groups. Vector One® receives over 2.0 billion prescription claims per year, representing over 160 million unique patients. Since 2002 Vector One® has captured information on over 8 billion prescriptions representing 200 million unique patients.

Prescriptions are captured from a sample of approximately 59,000 pharmacies throughout the US. The pharmacies in the data base account for nearly all retail pharmacies and represent nearly half of retail prescriptions dispensed nationwide. SDI receives all prescriptions from approximately one-third of the stores and a significant sample of prescriptions from the remaining stores.

SDI Vector One®: Total Patient Tracker (TPT)

SDI's Total Patient Tracker is a national-level projected audit designed to estimate the total number of unique patients across all drugs and therapeutic classes in the retail outpatient setting.

TPT derives its data from the Vector One® database which integrates prescription activity from a variety of sources including national retail chains, mail order pharmacies, mass merchandisers, pharmacy benefits managers and their data systems. Vector One® receives over 2 billion prescription claims per year, which represents over 160 million patients tracked across time.

SDI Physician Drug & Diagnosis Audit (PDDA) with Pain Panel

SDI's Physician Drug & Diagnosis Audit (PDDA) with Pain Panel is a monthly survey designed to provide descriptive information on the patterns and treatment of diseases encountered in office-based physician practices in the U.S. The survey consists of data collected from over 3,200 office-based physicians representing 30 specialties across the United States that report on all patient activity during one typical workday per month. These data may include profiles and trends of diagnoses, patients, drug products mentioned during the office visit and treatment patterns. The Pain Panel supplement surveys over 115 pain specialists physicians each month. With the inclusion of visits to pain specialists, this will allow additional insight into the pain market. The data are then projected nationally by physician specialty and region to reflect national prescribing patterns.

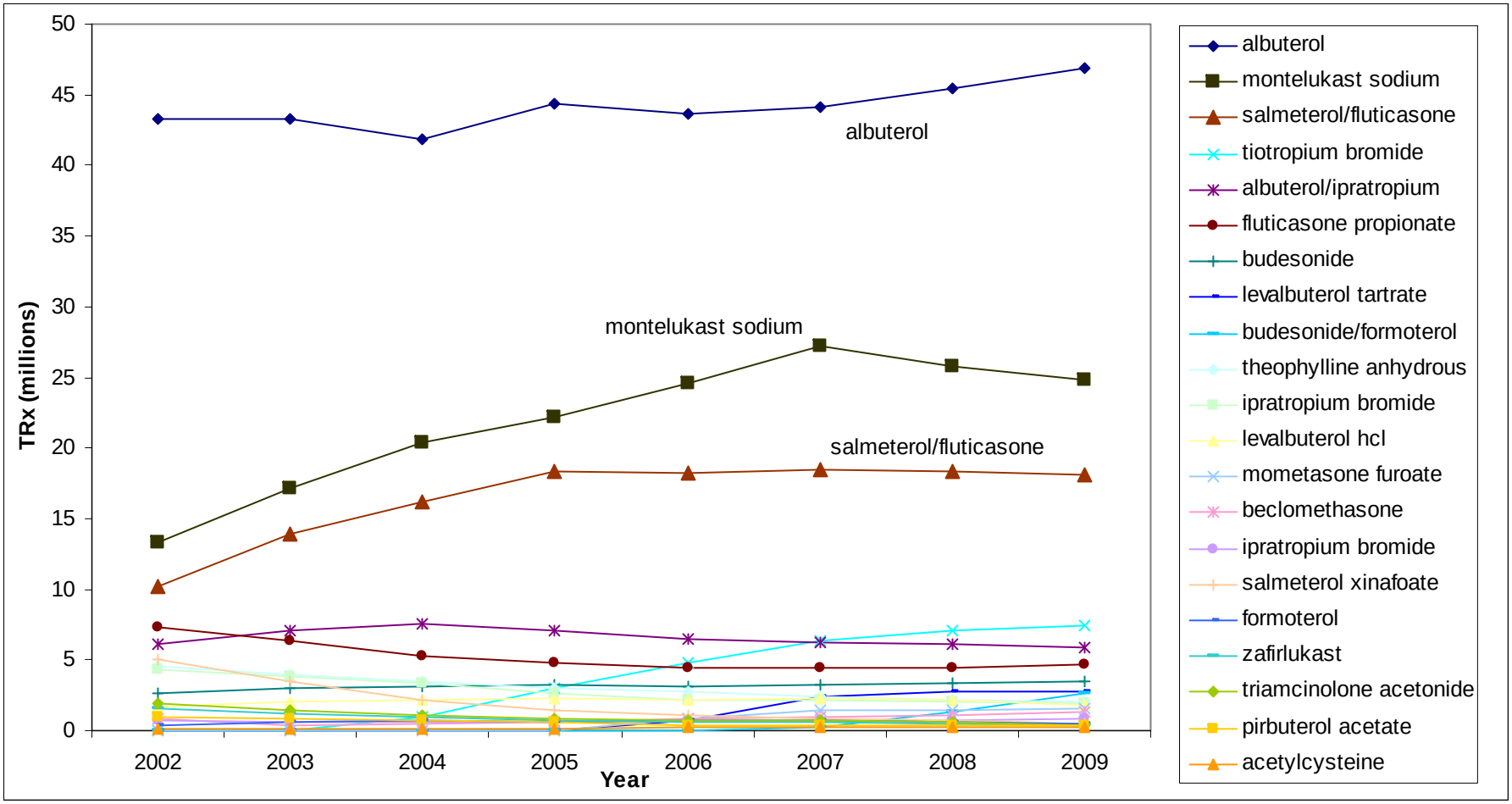
APPENDIX 2: TABLES AND FIGURES

Table 1: Total Dispensed Prescriptions for Top Asthma Medications for the Overall Population from U.S. Outpatient Retail Pharmacies, Years 2002-2009

	2002		2003		2004		2005		2006		2007		2008		2009		1/2002-12/2009	
	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*
	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*
TOTAL MARKET	106,862,941	*100%*	110,505,934	*100%*	111,645,545	*100%*	117,001,602	*100%*	119,542,634	*100%*	126,251,776	*100%*	127,595,143	*100%*	128,709,708	*100%*	948,115,283	*100%*
albuterol	43,327,233	*40.5%*	43,275,417	*39.2%*	41,821,745	*37.5%*	44,367,256	*37.9%*	43,631,970	*36.5%*	44,130,163	*35.0%*	45,431,928	*35.6%*	46,825,342	*36.4%*	352,811,054	*37.2%*
montelukast sodium	13,259,586	*12.4%*	17,196,725	*15.6%*	20,435,068	*18.3%*	22,167,166	*18.9%*	24,611,082	*20.6%*	27,254,994	*21.6%*	25,787,471	*20.2%*	24,820,023	*19.3%*	175,532,115	*18.5%*
salmeterol/fluticasone	**10,181,657**	***9.5%***	**13,931,094**	***12.6%***	**16,144,908**	***14.5%***	**18,289,379**	***15.6%***	**18,276,579**	***15.3%***	**18,515,465**	***14.7%***	**18,365,008**	***14.4%***	**18,116,514**	***14.1%***	**131,820,604**	***13.9%***
tiotropium bromide	--	--	--	--	914,904	*0.8%*	2,938,078	*2.5%*	4,741,068	*4.0%*	6,395,550	*5.1%*	7,121,148	*5.6%*	7,394,103	*5.7%*	29,504,851	*3.1%*
albuterol/ipratropium	6,170,500	*5.8%*	7,092,552	*6.4%*	7,496,289	*6.7%*	7,074,149	*6.0%*	6,481,779	*5.4%*	6,193,591	*4.9%*	6,153,900	*4.8%*	5,933,081	*4.6%*	52,595,841	*5.5%*
fluticasone propionate	7,285,046	*6.8%*	6,333,051	*5.7%*	5,298,285	*4.7%*	4,749,215	*4.1%*	4,446,924	*3.7%*	4,384,232	*3.5%*	4,426,165	*3.5%*	4,734,362	*3.7%*	41,657,280	*4.4%*
budesonide	2,603,694	*2.4%*	3,026,713	*2.7%*	3,176,788	*2.8%*	3,178,991	*2.7%*	3,165,533	*2.6%*	3,248,327	*2.6%*	3,347,061	*2.6%*	3,434,930	*2.7%*	25,182,037	*2.7%*
levalbuterol tartrate	--	--	--	--	--	--	5,063	*0.0%*	712,629	*0.6%*	2,370,604	*1.9%*	2,737,795	*2.1%*	2,801,651	*2.2%*	8,627,742	*0.9%*
budesonide/formoterol	--	--	--	--	--	--	--	--	--	--	**188,126**	***0.1%***	**1,366,390**	***1.1%***	**2,592,613**	***2.0%***	**4,147,129**	***0.4%***
theophylline anhydrous	4,529,408	*4.2%*	4,010,394	*3.6%*	3,451,705	*3.1%*	2,942,739	*2.5%*	2,710,742	*2.3%*	2,456,786	*1.9%*	2,214,636	*1.7%*	1,993,397	*1.5%*	24,309,807	*2.6%*
ipratropium bromide	4,341,918	*4.1%*	3,792,749	*3.4%*	3,297,381	*3.0%*	2,668,444	*2.3%*	2,174,677	*1.8%*	2,163,288	*1.7%*	2,026,859	*1.6%*	1,909,240	*1.5%*	22,374,556	*2.4%*
levalbuterol hcl	1,698,975	*1.6%*	2,075,796	*1.9%*	2,151,026	*1.9%*	2,274,838	*1.9%*	2,206,836	*1.8%*	2,316,304	*1.8%*	2,166,016	*1.7%*	1,809,360	*1.4%*	16,699,151	*1.8%*
mometasone furoate	--	--	--	--	--	--	55,827	*0.0%*	780,853	*0.7%*	1,416,372	*1.1%*	1,484,336	*1.2%*	1,500,948	*1.2%*	5,238,336	*0.6%*
beclomethasone	864,003	*0.8%*	336,270	*0.3%*	433,067	*0.4%*	613,539	*0.5%*	840,137	*0.7%*	949,574	*0.8%*	1,057,329	*0.8%*	1,366,653	*1.1%*	6,460,572	*0.7%*
ipratropium bromide	683,054	*0.6%*	635,612	*0.6%*	633,722	*0.6%*	656,645	*0.6%*	676,656	*0.6%*	724,199	*0.6%*	761,356	*0.6%*	824,811	*0.6%*	5,596,055	*0.6%*
salmeterol xinafoate	**5,005,037**	***4.7%***	**3,466,160**	***3.1%***	**2,180,914**	***2.0%***	**1,438,762**	***1.2%***	**1,047,763**	***0.9%***	**815,022**	***0.6%***	**672,777**	***0.5%***	**531,900**	***0.4%***	**15,158,335**	***1.6%***
formoterol	**415,372**	**0.4%**	**557,721**	**0.5%**	**680,972**	**0.6%**	**651,905**	**0.6%**	**715,301**	**0.6%**	**669,165**	**0.5%**	**594,172**	**0.5%**	**499,161**	**0.4%**	**4,783,769**	**0.5%**
zafirlukast	1,553,416	*1.5%*	1,181,491	*1.1%*	939,663	*0.8%*	767,558	*0.7%*	651,494	*0.5%*	557,226	*0.4%*	482,409	*0.4%*	416,690	*0.3%*	6,549,947	*0.7%*
triamcinolone acetonide	1,904,245	*1.8%*	1,473,948	*1.3%*	1,058,078	*0.9%*	878,095	*0.8%*	765,367	*0.6%*	673,326	*0.5%*	576,853	*0.5%*	368,206	*0.3%*	7,698,118	*0.8%*
pirbuterol acetate	957,453	*0.9%*	809,765	*0.7%*	681,217	*0.6%*	571,987	*0.5%*	380,252	*0.3%*	349,505	*0.3%*	324,969	*0.3%*	301,595	*0.2%*	4,376,743	*0.5%*
acetylcysteine	91,341	*0.1%*	113,275	*0.1%*	154,252	*0.1%*	170,881	*0.1%*	181,798	*0.2%*	201,302	*0.2%*	209,981	*0.2%*	217,019	*0.2%*	1,339,849	*0.1%*

Source: SDI Vector One®: National. Years 2002-2009, extracted Feb2010. File: VONA 2010-207 top asthma drugs.xls

Figure 1: Total Dispensed Prescriptions for Top Asthma Medications for the Overall Population from U.S. Outpatient Retail Pharmacies, Years 2002-2009



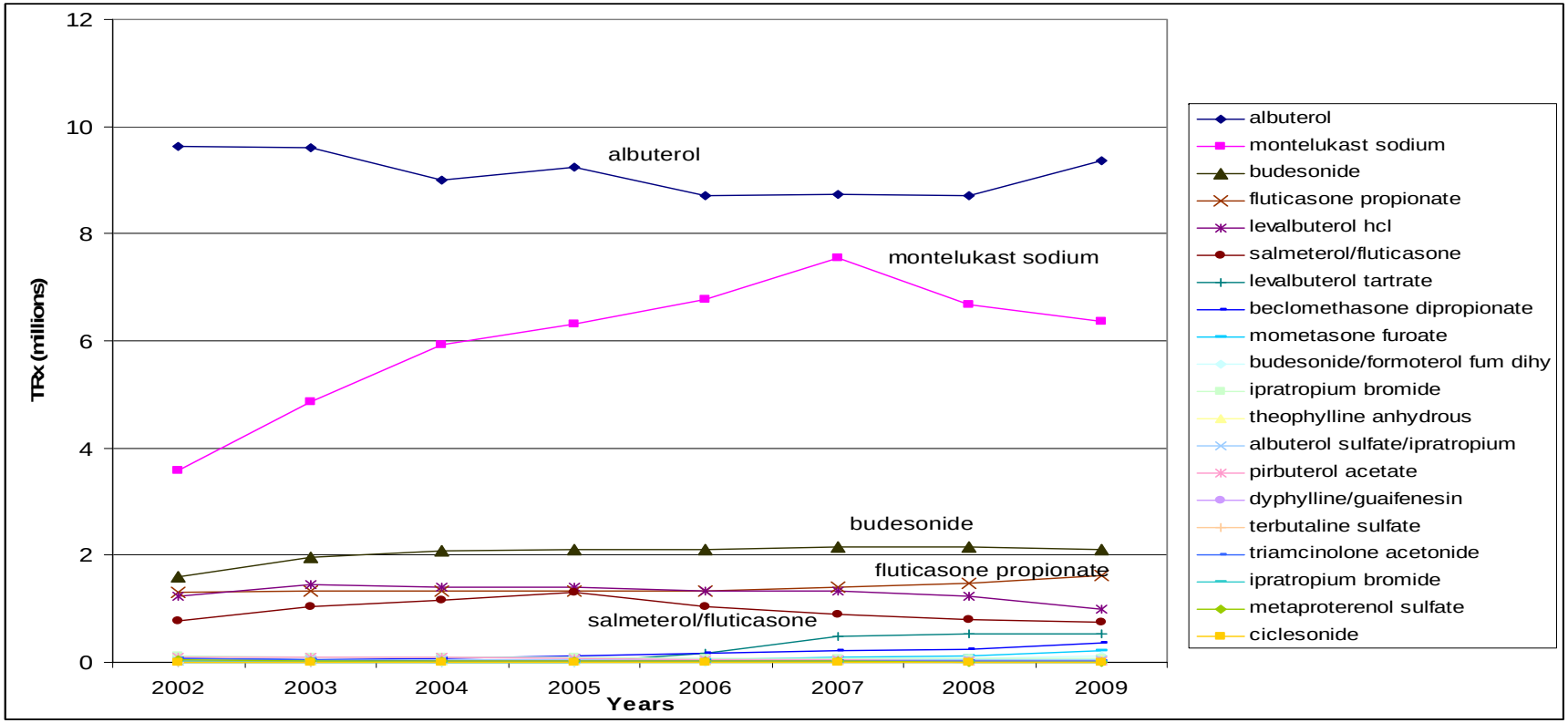
Source: SDI Vector One®: National. Years 2002-2009, extracted Feb2010. File: VONA 2010-207 top asthma drugs.xls

Table 2: Total Dispensed Prescriptions in the Asthma Market by Patient Age from U.S. Outpatient Retail Pharmacies, Years 2002-2009

	2002		2003		2004		2005		2006		2007		2008		2009		1/2002-12/2009	
	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Asthma Market	106,875,036	*100.0%*	110,509,299	*100.0%*	111,644,882	*100.0%*	117,001,532	*100.0%*	119,541,963	*100.0%*	126,251,746	*100.0%*	127,595,062	*100.0%*	128,709,599	*100.0%*	948,129,119	*100.0%*
Age: 0-11 years	19,283,334	*18.0%*	21,032,061	*19.0%*	21,515,691	*19.3%*	22,278,218	*19.0%*	22,046,762	*18.4%*	23,226,979	*18.4%*	22,368,438	*17.5%*	22,721,742	*17.7%*	174,473,225	*18.4%*
Age: 12+ years	86,971,226	*81.4%*	88,919,325	*80.5%*	88,961,403	*79.7%*	93,405,315	*79.8%*	96,794,671	*81.0%*	102,503,369	*81.2%*	104,767,925	*82.1%*	105,520,004	*82.0%*	767,843,238	*81.0%*
Unspecified Age	620,476	*0.6%*	557,913	*0.5%*	1,167,788	*1.0%*	1,317,999	*1.1%*	700,530	*0.6%*	521,398	*0.4%*	458,699	*0.4%*	467,853	*0.4%*	5,812,656	*0.6%*

Source: SDI Vector One®: National. Years 2002-2009, extracted Feb2010. File: VONA 2010-207 top asthma drugs by age.xls

Figure 2: Total Dispensed Prescriptions for Top Asthma Medications for Pediatric Patients (0-11 years old) from U.S. Outpatient Retail Pharmacies, Years 2002-2009 (Table not shown)



Source: SDI Vector One®: National. Years 2002-2009, extracted Feb2010. File: VONA 2010-207 top asthma drugs by age.xls

Table 3: Part 1: Total Dispensed Prescriptions for Salmeterol and Formoterol Products (LABAs) by Patient Age (0-11 years old) from U.S. Outpatient Retail Pharmacies, Years 2002-2009

Molecule	Year 2002		Year 2003		Year 2004		Year 2005		Year 2006		Year 2007		Year 2008		Year 2009		1/2002-12/2009	
Product	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*
Strength	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
TOTAL MARKET	15,602,186	*100.0%*	17,954,982	*100.0%*	19,006,786	*100.0%*	20,380,034	*100.0%*	20,039,310	*100.0%*	20,187,617	*100.0%*	20,998,185	*100.0%*	21,740,170	*100.0%*	155,909,270	*100.0%*
Age: 0-11 years	1,024,787	*6.6%*	1,201,790	*6.7%*	1,255,367	*6.6%*	1,378,617	*6.8%*	1,093,363	*5.5%*	951,145	*4.7%*	899,595	*4.3%*	872,780	*4.0%*	8,677,444	*5.6%*
salmeterol/ fluticasone	780,731	*76.2%*	1,033,299	*86.0%*	1,158,081	*92.3%*	1,311,242	*95.1%*	1,045,043	*95.6%*	905,511	*95.2%*	803,679	*89.3%*	740,647	*84.9%*	7,778,233	*89.6%*
Advair Diskus	780,731	*100.0%*	1,033,299	*100.0%*	1,158,081	*100.0%*	1,311,242	*100.0%*	1,037,903	*99.3%*	813,938	*89.9%*	648,609	*80.7%*	547,962	*74.0%*	7,331,765	*94.3%*
100/50MCG	563,240	*72.1%*	742,521	*71.9%*	827,178	*71.4%*	947,002	*72.2%*	739,894	*71.3%*	571,602	*70.2%*	448,795	*69.2%*	372,500	*68.0%*	5,212,732	*71.1%*
250/50MCG	195,247	*25.0%*	262,934	*25.4%*	299,488	*25.9%*	332,403	*25.4%*	271,888	*26.2%*	221,082	*27.2%*	183,287	*28.3%*	160,639	*29.3%*	1,926,968	*26.3%*
500/50MCG	22,244	*2.8%*	27,844	*2.7%*	31,415	*2.7%*	31,837	*2.4%*	26,121	*2.5%*	21,254	*2.6%*	16,527	*2.5%*	14,823	*2.7%*	192,065	*2.6%*
Advair HFA	--	--	--	--	--	--	--	--	7,140	*0.7%*	91,573	*10.1%*	155,070	*19.3%*	192,685	*26.0%*	446,468	*5.7%*
115/21MCG	--	--	--	--	--	--	--	--	3,493	*48.9%*	44,081	*48.1%*	76,714	*49.5%*	96,904	*50.3%*	221,192	*49.5%*
45/21MCG	--	--	--	--	--	--	--	--	3,126	*43.8%*	39,386	*43.0%*	63,730	*41.1%*	75,339	*39.1%*	181,581	*40.7%*
230/21MCG	--	--	--	--	--	--	--	--	521	*7.3%*	8,106	*8.9%*	14,626	*9.4%*	20,442	*10.6%*	43,695	*9.8%*
budesonide/ formoterol	--	--	--	--	--	--	--	--	--	--	13,278	*1.4%*	74,591	*8.3%*	117,286	*13.4%*	205,155	*2.4%*
Symbicort	--	--	--	--	--	--	--	--	--	--	13,278	*100.0%*	74,591	*100.0%*	117,286	*100.0%*	205,155	*100.0%*
80/4.5MCG	--	--	--	--	--	--	--	--	--	--	7,386	*55.6%*	41,014	*55.0%*	63,046	*53.8%*	111,446	*54.3%*
160/4.5MCG	--	--	--	--	--	--	--	--	--	--	5,892	*44.4%*	33,577	*45.0%*	54,240	*46.2%*	93,709	*45.7%*
formoterol	32,936	*3.2%*	43,909	*3.7%*	57,008	*4.5%*	48,190	*3.5%*	38,830	*3.6%*	26,832	*2.8%*	17,915	*2.0%*	12,616	*1.4%*	278,236	*3.2%*
Foradil	32,936	*100.0%*	43,909	*100.0%*	57,008	*100.0%*	48,190	*100.0%*	38,830	*100.0%*	26,761	*99.7%*	17,060	*95.2%*	11,792	*93.5%*	276,486	*99.4%*
Perforomist	--	--	--	--	--	--	--	--	--	--	71	*0.3%*	855	*4.8%*	824	*6.5%*	1,750	*0.6%*
salmeterol	211,120	*20.6%*	124,582	*10.4%*	40,278	*3.2%*	19,185	*1.4%*	9,490	*0.9%*	5,524	*0.6%*	3,410	*0.4%*	2,231	*0.3%*	415,820	*4.8%*
Serevent Diskus	38,642	*18.3%*	45,919	*36.9%*	39,929	*99.1%*	19,161	*99.9%*	9,484	*99.9%*	5,524	*100.0%*	3,410	*100.0%*	2,231	*100.0%*	164,300	*39.5%*
Serevent	172,478	*81.7%*	78,663	*63.1%*	349	*0.9%*	24	*0.1%*	6	*0.1%*	--	--	--	--	--	--	251,520	*60.5%*

Source: SDI Vector One®: National. Years 2002-2009, extracted Feb2010. File: VONA 2010-207 LABA age, prod, strength.xls

Table 3: Part 2: Total Dispensed Prescriptions for Salmeterol and Formoterol Products (LABAs) by Patient Age (12+ years old) from U.S. Outpatient Retail Pharmacies, Years 2002-2009

Molecule	Year 2002		Year 2003		Year 2004		Year 2005		Year 2006		Year 2007		Year 2008		Year 2009		1/2002-12/2009	
Product	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*
Strength	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*
Age: 12+ years	14,534,137	*93.2%*	16,693,258	*93.0%*	17,592,396	*92.6%*	18,808,720	*92.3%*	18,863,212	*94.1%*	19,178,291	*95.0%*	20,046,785	*95.5%*	20,815,759	*95.7%*	146,532,558	*94.0%*
salmeterol/ fluticasone	9,365,970	*64.4%*	12,852,070	*77.0%*	14,855,661	*84.4%*	16,807,254	*89.4%*	17,156,162	*91.0%*	17,557,355	*91.5%*	17,515,539	*87.4%*	17,332,342	*83.3%*	123,442,353	*84.2%*
Advair Diskus	9,365,970	*100.0%*	12,852,070	*100.0%*	14,855,661	*100.0%*	16,807,254	*100.0%*	17,136,187	*99.9%*	17,315,435	*98.6%*	17,127,061	*97.8%*	16,821,627	*97.1%*	122,281,265	*99.1%*
250/50MCG	4,422,390	*47.2%*	6,221,133	*48.4%*	7,576,077	*51.0%*	8,984,040	*53.5%*	9,525,701	*55.6%*	9,970,363	*57.6%*	10,146,492	*59.2%*	10,219,255	*60.8%*	67,065,451	*54.8%*
100/50MCG	3,370,291	*36.0%*	4,493,303	*35.0%*	4,812,825	*32.4%*	5,114,904	*30.4%*	4,781,847	*27.9%*	4,383,907	*25.3%*	3,969,560	*23.2%*	3,619,509	*21.5%*	34,546,146	*28.3%*
500/50MCG	1,573,289	*16.8%*	2,137,634	*16.6%*	2,466,759	*16.6%*	2,708,310	*16.1%*	2,828,639	*16.5%*	2,961,165	*17.1%*	3,011,009	*17.6%*	2,982,863	*17.7%*	20,669,668	*16.9%*
Advair HFA	--	--	--	--	--	--	--	--	19,975	*0.1%*	241,920	*1.4%*	388,478	*2.2%*	510,715	*2.9%*	1,161,088	*0.9%*
115/21MCG	--	--	--	--	--	--	--	--	13,420	*67.2%*	146,903	*60.7%*	218,408	*56.2%*	287,368	*56.3%*	666,099	*57.4%*
230/21MCG	--	--	--	--	--	--	--	--	2,220	*11.1%*	48,933	*20.2%*	99,433	*25.6%*	139,525	*27.3%*	290,111	*25.0%*
45/21MCG	--	--	--	--	--	--	--	--	4,335	*21.7%*	46,084	*19.0%*	70,637	*18.2%*	83,822	*16.4%*	204,878	*17.6%*
budesonide/ formoterol	--	--	--	--	--	--	--	--	--	--	174,250	*0.9%*	1,288,668	*6.4%*	2,469,753	*11.9%*	3,932,671	*2.7%*
Symbicort	--	--	--	--	--	--	--	--	--	--	174,250	*100.0%*	1,288,668	*100.0%*	2,469,753	*100.0%*	3,932,671	*100.0%*
160/4.5MCG	--	--	--	--	--	--	--	--	--	--	124,012	*71.2%*	946,484	*73.4%*	1,889,686	*76.5%*	2,960,182	*75.3%*
80/4.5MCG	--	--	--	--	--	--	--	--	--	--	50,238	*28.8%*	342,184	*26.6%*	580,067	*23.5%*	972,489	*24.7%*
salmeterol	4,788,059	*32.9%*	3,330,055	*19.9%*	2,119,081	*12.0%*	1,403,073	*7.5%*	1,033,207	*5.5%*	806,646	*4.2%*	667,685	*3.3%*	528,391	*2.5%*	14,676,197	*10.0%*
Serevent Diskus	440,952	*9.2%*	1,528,968	*45.9%*	2,110,518	*99.6%*	1,401,561	*99.9%*	1,032,894	*100.0%*	806,563	*100.0%*	667,642	*100.0%*	528,320	*100.0%*	8,517,418	*58.0%*
Serevent	4,347,107	*90.8%*	1,801,087	*54.1%*	8,563	*0.4%*	1,512	*0.1%*	313	*0.0%*	83	*0.0%*	43	*0.0%*	71	*0.0%*	6,158,779	*42.0%*
formoterol	380,108	*2.6%*	511,133	*3.1%*	617,654	*3.5%*	598,393	*3.2%*	673,843	*3.6%*	640,040	*3.3%*	574,893	*2.9%*	485,273	*2.3%*	4,481,337	*3.1%*
Foradil	380,108	*100.0%*	511,133	*100.0%*	617,654	*100.0%*	598,393	*100.0%*	673,843	*100.0%*	638,533	*99.8%*	551,113	*95.9%*	446,173	*91.9%*	4,416,950	*98.6%*
Perforomist	--	--	--	--	--	--	--	--	--	--	1,507	*0.2%*	23,718	*4.1%*	38,658	*8.0%*	63,883	*1.4%*
Formoterol	--	--	--	--	--	--	--	--	--	--	--	--	62	*0.0%*	442	*0.1%*	504	*0.0%*
Unspecified Age	43,262	*0.3%*	59,934	*0.3%*	159,023	*0.8%*	192,697	*0.9%*	82,735	*0.4%*	58,181	*0.3%*	51,805	*0.2%*	51,631	*0.2%*	699,268	*0.4%*

Source: SDI Vector One®: National. Years 2002-2009, extracted Feb2010. File: VONA 2010-207 LABA age, prod, strength.xls

Table 4: Total Number of Unique Patients Receiving Salmeterol and Formoterol Products (LABAs) from U.S. Outpatient Retail Settings by Patient Age, Years 2002-2009

	2002		2003		2004		2005		2006		2007		2008		2009		1/2002-12/2009	
	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*
	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*
LABA Total	4,945,119	*100.0%*	5,856,849	*100.0%*	5,783,787	*100.0%*	6,276,190	*100.0%*	5,962,981	*100.0%*	5,953,348	*100.0%*	6,296,403	*100.0%*	6,176,295	*100.0%*	**23,155,541**	*100.0%*
Age: 0-11 years	409,389	*8.3%*	489,502	*8.4%*	503,737	*8.7%*	545,606	*8.7%*	420,780	*7.1%*	369,575	*6.2%*	350,452	*5.6%*	322,478	*5.2%*	2,010,077	8.7%
salmeterol/ fluticasone	309,982	*75.7%*	420,589	*85.9%*	468,108	*92.9%*	522,705	*95.8%*	404,587	*96.2%*	351,925	*95.2%*	312,950	*89.3%*	275,257	*85.4%*	1,806,127	*89.9%*
Advair Diskus	309,982	*100.0%*	420,589	*100.0%*	468,108	*100.0%*	522,705	*100.0%*	399,953	*98.9%*	316,813	*90.0%*	258,060	*82.5%*	213,188	*77.5%*	1,707,237	*94.5%*
Advair HFA		*0.0%*		*0.0%*		*0.0%*		*0.0%*	5,689	*1.4%*	40,419	*11.5%*	60,844	*19.4%*	68,744	*25.0%*	128,266	*7.1%*
budesonide/ formoterol		*0.0%*		*0.0%*		*0.0%*		*0.0%*		*0.0%*	8,755	*2.4%*	34,164	*9.7%*	47,002	*14.6%*	72,169	*3.6%*
Symbicort		*0.0%*		*0.0%*		*0.0%*		*0.0%*		*0.0%*	8,755	*100.0%*	34,164	*100.0%*	47,002	*100.0%*	72,169	*100.0%*
formoterol	17,161	*4.2%*	23,059	*4.7%*	25,573	*5.1%*	19,722	*3.6%*	14,902	*3.5%*	10,870	*2.9%*	7,911	*2.3%*	5,524	*1.7%*	86,702	*4.3%*
Foradil	17,161	*100.0%*	23,059	*100.0%*	25,573	*100.0%*	19,722	*100.0%*	14,902	*100.0%*	10,829	*99.6%*	7,553	*95.5%*	5,198	*94.1%*	86,144	*99.4%*
Perforomist		*0.0%*		*0.0%*		*0.0%*		*0.0%*		*0.0%*	59	*0.5%*	388	*4.9%*	327	*5.9%*	652	*0.8%*
salmeterol	99,144	*24.2%*	62,047	*12.7%*	17,480	*3.5%*	7,979	*1.5%*	3,864	*0.9%*	2,229	*0.6%*	1,520	*0.4%*	1,011	*0.3%*	150,617	*7.5%*
Serevent	83,151	*83.9%*	45,212	*72.9%*	289	*1.7%*	22	*0.3%*	7	*0.2%*		*0.0%*		*0.0%*		*0.0%*	107,135	*71.1%*
Serevent Diskus	17,057	*17.2%*	24,565	*39.6%*	17,295	*98.9%*	7,970	*99.9%*	3,861	*99.9%*	2,229	*100.0%*	1,520	*100.0%*	1,011	*100.0%*	56,288	*37.4%*
Age: 12+ years	4,550,294	*92.0%*	5,368,093	*91.7%*	5,249,938	*90.8%*	5,693,294	*90.7%*	5,535,086	*92.8%*	5,581,714	*93.8%*	5,937,666	*94.3%*	5,784,241	*93.7%*	21,422,374	92.5%
salmeterol/ fluticasone	3,116,181	*68.5%*	4,329,906	*80.7%*	4,635,569	*88.3%*	5,269,725	*92.6%*	5,176,252	*93.5%*	5,212,784	*93.4%*	5,209,339	*87.7%*	4,774,535	*82.5%*	18,880,517	*88.1%*
Advair Diskus	3,116,181	*100.0%*	4,329,906	*100.0%*	4,635,569	*100.0%*	5,269,725	*100.0%*	5,165,250	*99.8%*	5,121,726	*98.3%*	5,080,909	*97.5%*	4,624,014	*96.8%*	18,685,631	*99.0%*
Advair HFA		*0.0%*		*0.0%*		*0.0%*		*0.0%*	16,713	*0.3%*	125,537	*2.4%*	163,245	*3.1%*	185,951	*3.9%*	387,177	*2.1%*
budesonide /formoterol		*0.0%*		*0.0%*		*0.0%*		*0.0%*		*0.0%*	115,864	*2.1%*	581,402	*9.8%*	965,761	*16.7%*	1,393,699	*6.5%*
Symbicort		*0.0%*		*0.0%*		*0.0%*		*0.0%*		*0.0%*	115,864	*100.0%*	581,402	*100.0%*	965,761	*100.0%*	1,393,699	*100.0%*
formoterol	145,054	*3.2%*	199,646	*3.7%*	198,463	*3.8%*	177,295	*3.1%*	190,567	*3.4%*	168,767	*3.0%*	155,115	*2.6%*	120,358	*2.1%*	835,208	*3.9%*
Formoterol		*0.0%*		*0.0%*		*0.0%*		*0.0%*		*0.0%*		*0.0%*	19	*0.0%*	64	*0.1%*	72	*0.0%*
Foradil	145,054	*100.0%*	199,646	*100.0%*	198,463	*100.0%*	177,295	*100.0%*	190,567	*100.0%*	167,859	*99.5%*	145,946	*94.1%*	107,544	*89.4%*	817,144	*97.8%*
Perforomist		*0.0%*		*0.0%*		*0.0%*		*0.0%*		*0.0%*	1,141	*0.7%*	10,312	*6.6%*	13,265	*11.0%*	21,414	*2.6%*
salmeterol	1,593,166	*35.0%*	1,123,488	*20.9%*	571,228	*10.9%*	352,854	*6.2%*	252,088	*4.6%*	187,186	*3.4%*	157,839	*2.7%*	118,233	*2.0%*	2,600,029	*12.1%*
Serevent	1,462,803	*91.8%*	823,945	*73.3%*	5,979	*1.0%*	947	*0.3%*	226	*0.1%*	77	*0.0%*	38	*0.0%*	58	*0.0%*	1,780,977	*68.5%*
Serevent Diskus	143,647	*9.0%*	626,579	*55.8%*	568,309	*99.5%*	352,423	*99.9%*	251,987	*100.0%*	187,159	*100.0%*	157,822	*100.0%*	118,214	*100.0%*	1,335,752	*51.4%*
Unknown Age	19,012	*0.4%*	57,186	*1.0%*	118,766	*2.1%*	137,545	*2.2%*	84,361	*1.4%*	76,962	*1.3%*	80,931	*1.3%*	180,259	*2.9%*	487,043	2.1%

*Subtotals may not sum exactly, due to rounding. Due to aging of patients during the study period ("the cohort effect"), patients may be counted more than once in the individual age categories. For this reason, summing across age bands is not advisable and will result in overestimates of patient counts

Source: SDI: Total Patient Tracker, 2002-2009, Extracted Feb10. Files: TPT 2010-207 pt by age, mol, product total.xls, TPT 2010-207 pt by age, mol, product years.xls, TPT LABA Patients -formoterol molecule total.xls, TPT LABA Patients -formoterol molecule years.xls, TPT LABA Patients formoterol only years.xls, TPT LABA Patients formoterol only total.xls, TPT LABA Patients by age years.xls, TPT LABA Patients by age total.xls

Table 5: Total Dispensed Prescriptions for Salmeterol and Formoterol-containing products (LABAs) from U.S. Outpatient Retail Pharmacies by Prescribing Specialties, Years 2002-2009

	1/2002-12/2009	
	TRxs	*Share*
	N	*%*
TOTAL MARKET	155,909,698	*100.0%*
GP/FM/DO	46,552,294	*29.9%*
IM	35,329,736	*22.7%*
PUD	19,791,181	*12.7%*
UNSPEC	12,177,097	*7.8%*
PED	10,941,365	*7.0%*
ALLER/IMMU	9,628,595	*6.2%*
NP	4,425,194	*2.8%*
PA	3,117,800	*2.0%*
ALLER	2,467,521	*1.6%*
HOSP	2,340,419	*1.5%*
All Others	9,138,496	*5.9%*

Source: SDI Vector One®: National. Years 2002-2009, extracted Feb2010. File: VONA 2010-207 LABA MD.xls

Table 6: Diagnoses Associated with the Use of Salmeterol and Formoterol-containing products (LABAs) in Number of Drug Uses by Patient Age As Reported by U.S. Office-Based Physician Practices, Years 2002-2009

	1/2002-12/2009	
	Uses	Share
	N(000)	%
TOTAL MARKET	100,273	100.0%
Age: 0-11 years	7,034	7.0%
4939 ASTHMA NOS	5,571	79.2%
7862 COUGH	319	4.5%
4900 BRONCHITIS NOS	290	4.1%
7860 DYSPNEA/RESPIRATORY ABN	143	2.0%
5191 OTH DIS TRACHEA /BRON	84	1.2%
4931 INTRINSIC ASTHMA	80	1.1%
All Others	546	7.8%
Age: 12+ years	93,239	93.0%
4939 ASTHMA NOS	52,492	56.3%
4960 CHR AIRWAY OBSTRUCT NEC	20,654	22.2%
4900 BRONCHITIS NOS	3,370	3.6%
7862 COUGH	2,711	2.9%
4919 CHRONIC BRONCHITIS NOS	2,271	2.4%
7860 DYSPNEA/RESPIRATORY ABN	1,995	2.1%
4912 OBSTRUCT CHR BRONCHITIS	1,362	1.5%
5191 OTH DIS TRACHEA /BRON	1,052	1.1%
All Others	7,331	7.9%

Source: SDI Physician Drug and Diagnosis Audit. Years 2002-2009. Extracted Feb2010. File: PDDA 2010-207 LABA DX.xls

Table 7 Part 1: Total Dispensed Prescriptions for Selected Inhaled Corticosteroid Products by Patient Age (0-11 years old) from U.S. Outpatient Retail Pharmacies, Years 2002-2009

Molecule	2002		2003		2004		2005		2006		2007		2008		2009		1/2002-12/2009	
Product	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*
Strength	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
TOTAL MARKET	23,423,800	*100.0%*	25,559,437	*100.0%*	26,448,994	*100.0%*	28,017,214	*100.0%*	28,464,669	*100.0%*	29,525,722	*100.0%*	30,744,561	*100.0%*	32,287,075	*100.0%*	224,471,472	*100.0%*
Age: 0-11 years	3,854,491	*16.5%*	4,420,690	*17.3%*	4,675,101	*17.7%*	4,912,859	*17.5%*	4,730,677	*16.6%*	4,798,217	*16.3%*	4,923,014	*16.0%*	5,184,130	*16.1%*	37,499,179	*16.7%*
budesonide	1,599,924	*41.5%*	1,962,551	*44.4%*	2,083,633	*44.6%*	2,115,800	*43.1%*	2,095,603	*44.3%*	2,141,494	*44.6%*	2,147,092	*43.6%*	2,109,537	*40.7%*	16,255,634	*43.3%*
Pulmicort Respules	1,467,524	*91.7%*	1,817,333	*92.6%*	1,946,866	*93.4%*	1,986,773	*93.9%*	1,954,758	*93.3%*	1,994,963	*93.2%*	1,882,296	*87.7%*	1,399,587	*66.3%*	14,450,100	*88.9%*
0.5MG	636,054	*43.3%*	875,523	*48.2%*	1,018,358	*52.3%*	1,089,093	*54.8%*	1,103,525	*56.5%*	1,141,371	*57.2%*	1,080,513	*57.4%*	793,767	*56.7%*	7,738,204	*53.6%*
0.25MG	831,470	*56.7%*	941,810	*51.8%*	928,508	*47.7%*	897,680	*45.2%*	851,233	*43.5%*	846,961	*42.5%*	745,577	*39.6%*	529,681	*37.8%*	6,572,920	*45.5%*
1MG	--	--	--	--	--	--	--	--	--	--	6,631	*0.3%*	56,206	*3.0%*	76,139	*5.4%*	138,976	*1.0%*
Budesonide	--	--	--	--	--	--	--	--	--	--	--	--	100,119	*4.7%*	555,883	*26.4%*	656,002	*4.0%*
0.5MG	--	--	--	--	--	--	--	--	--	--	--	--	61,277	*61.2%*	350,747	*63.1%*	412,024	*62.8%*
0.25MG	--	--	--	--	--	--	--	--	--	--	--	--	38,842	*38.8%*	205,136	*36.9%*	243,978	*37.2%*
Pulmicort Flexhaler	--	--	--	--	--	--	--	--	--	--	74,631	*3.5%*	163,714	*7.6%*	153,965	*7.3%*	392,310	*2.4%*
180 MCG	--	--	--	--	--	--	--	--	--	--	55,386	*74.2%*	108,386	*66.2%*	92,351	*60.0%*	256,123	*65.3%*
90MCG	--	--	--	--	--	--	--	--	--	--	19,245	*25.8%*	55,328	*33.8%*	61,614	*40.0%*	136,187	*34.7%*
All Others	132,400	*8.3%*	145,218	*7.4%*	136,767	*6.6%*	129,027	*6.1%*	140,845	*6.7%*	71,900	*3.4%*	963	*0.0%*	102	*0.0%*	757,222	*4.7%*
fluticasone	1,317,968	*34.2%*	1,325,464	*30.0%*	1,323,567	*28.3%*	1,329,642	*27.1%*	1,324,036	*28.0%*	1,391,892	*29.0%*	1,486,352	*30.2%*	1,621,416	*31.3%*	11,120,337	*29.7%*
Flovent HFA	--	--	--	--	--	--	827,634	*62.2%*	1,312,841	*99.2%*	1,388,191	*99.7%*	1,475,110	*99.2%*	1,597,224	*98.5%*	6,601,000	*59.4%*
44MCG	--	--	--	--	--	--	517,730	*62.6%*	792,581	*60.4%*	841,856	*60.6%*	903,246	*61.2%*	988,245	*61.9%*	4,043,658	*61.3%*
110MCG	--	--	--	--	--	--	285,535	*34.5%*	477,695	*36.4%*	504,800	*36.4%*	530,209	*35.9%*	568,525	*35.6%*	2,366,764	*35.9%*
220MCG	--	--	--	--	--	--	24,369	*2.9%*	42,565	*3.2%*	41,535	*3.0%*	41,655	*2.8%*	40,454	*2.5%*	190,578	*2.9%*
Flovent Diskus	--	--	--	--	--	--	--	--	--	--	1,995	*0.1%*	10,653	*0.7%*	23,856	*1.5%*	36,504	*0.3%*
50MCG	--	--	--	--	--	--	--	--	--	--	1,995	*100.0%*	10,653	*100.0%*	19,740	*82.7%*	32,388	*88.7%*
100MCG	--	--	--	--	--	--	--	--	--	--	--	--	--	--	3,870	*16.2%*	3,870	*10.6%*
250MCG	--	--	--	--	--	--	--	--	--	--	--	--	--	--	246	*1.0%*	246	*0.7%*
All Others	1,317,968	*100.0%*	1,325,464	*100.0%*	1,323,567	*100.0%*	502,008	*37.8%*	11,195	*0.8%*	1,706	*0.1%*	589	*0.0%*	336	*0.0%*	4,482,833	*40.3%*
salmeterol/fluticasone	780,731	*20.3%*	1,033,299	*23.4%*	1,158,081	*24.8%*	1,311,242	*26.7%*	1,045,043	*22.1%*	905,511	*18.9%*	803,679	*16.3%*	740,647	*14.3%*	7,778,233	*20.7%*
Advair Diskus	780,731	*100.0%*	1,033,299	*100.0%*	1,158,081	*100.0%*	1,311,242	*100.0%*	1,037,903	*99.3%*	813,938	*89.9%*	648,609	*80.7%*	547,962	*74.0%*	7,331,765	*94.3%*
100/50MCG	563,240	*72.1%*	742,521	*71.9%*	827,178	*71.4%*	947,002	*72.2%*	739,894	*71.3%*	571,602	*70.2%*	448,795	*69.2%*	372,500	*68.0%*	5,212,732	*71.1%*
250/50MCG	195,247	*25.0%*	262,934	*25.4%*	299,488	*25.9%*	332,403	*25.4%*	271,888	*26.2%*	221,082	*27.2%*	183,287	*28.3%*	160,639	*29.3%*	1,926,968	*26.3%*
500/50MCG	22,244	*2.8%*	27,844	*2.7%*	31,415	*2.7%*	31,837	*2.4%*	26,121	*2.5%*	21,254	*2.6%*	16,527	*2.5%*	14,823	*2.7%*	192,065	*2.6%*
Advair HFA	--	--	--	--	--	--	--	--	7,140	*0.7%*	91,573	*10.1%*	155,070	*19.3%*	192,685	*26.0%*	446,468	*5.7%*
115/21MCG	--	--	--	--	--	--	--	--	3,493	*48.9%*	44,081	*48.1%*	76,714	*49.5%*	96,904	*50.3%*	221,192	*49.5%*
45/21MCG	--	--	--	--	--	--	--	--	3,126	*43.8%*	39,386	*43.0%*	63,730	*41.1%*	75,339	*39.1%*	181,581	*40.7%*
230/21MCG	--	--	--	--	--	--	--	--	521	*7.3%*	8,106	*8.9%*	14,626	*9.4%*	20,442	*10.6%*	43,695	*9.8%*
beclomethasone	78,471	*2.0%*	41,881	*0.9%*	74,084	*1.6%*	120,514	*2.5%*	180,153	*3.8%*	211,735	*4.4%*	248,493	*5.0%*	353,483	*6.8%*	1,308,814	*3.5%*
Qvar	11,915	*15.2%*	39,599	*94.6%*	74,049	*100.0%*	120,508	*100.0%*	180,153	*100.0%*	211,722	*100.0%*	248,493	*100.0%*	353,483	*100.0%*	1,239,922	*94.7%*
40MCG	8,021	*67.3%*	30,926	*78.1%*	56,392	*76.2%*	90,400	*75.0%*	133,190	*73.9%*	152,433	*72.0%*	176,513	*71.0%*	250,337	*70.8%*	898,212	*72.4%*
80MCG	3,894	*32.7%*	8,673	*21.9%*	17,657	*23.8%*	30,108	*25.0%*	46,963	*26.1%*	59,289	*28.0%*	71,980	*29.0%*	103,146	*29.2%*	341,710	*27.6%*
All Others	66,556	*84.8%*	2,282	*5.4%*	35	*0.0%*	6	*0.0%*	--	--	13	*0.0%*	--	--	--	--	68,892	*5.3%*
mometasone	--	--	--	--	--	--	4,034	*0.1%*	53,141	*1.1%*	98,262	*2.0%*	130,192	*2.6%*	216,822	*4.2%*	502,451	*1.3%*
Asmanex	--	--	--	--	--	--	4,034	*100.0%*	53,141	*100.0%*	98,262	*100.0%*	130,192	*100.0%*	216,822	*100.0%*	502,451	*100.0%*
110MCG	--	--	--	--	--	--	--	--	--	--	--	--	29,623	*22.8%*	128,101	*59.1%*	157,724	*31.4%*
220MCG	--	--	--	--	--	--	4,034	*100.0%*	53,141	*100.0%*	98,262	*100.0%*	100,569	*77.2%*	88,721	*40.9%*	344,727	*68.6%*
budesonide/formoterol	--	--	--	--	--	--	--	--	--	--	13,278	*0.3%*	74,591	*1.5%*	117,286	*2.3%*	205,155	*0.5%*
Symbicort	--	--	--	--	--	--	--	--	--	--	13,278	*100.0%*	74,591	*100.0%*	117,286	*100.0%*	205,155	*100.0%*
80/4.5MCG	--	--	--	--	--	--	--	--	--	--	7,386	*55.6%*	41,014	*55.0%*	63,046	*53.8%*	111,446	*54.3%*
160/4.5MCG	--	--	--	--	--	--	--	--	--	--	5,892	*44.4%*	33,577	*45.0%*	54,240	*46.2%*	93,709	*45.7%*
All Others	77,397	*2.0%*	57,495	*1.3%*	35,736	*0.8%*	31,627	*0.6%*	32,701	*0.7%*	36,045	*0.8%*	32,615	*0.7%*	24,939	*0.5%*	328,555	*0.9%*

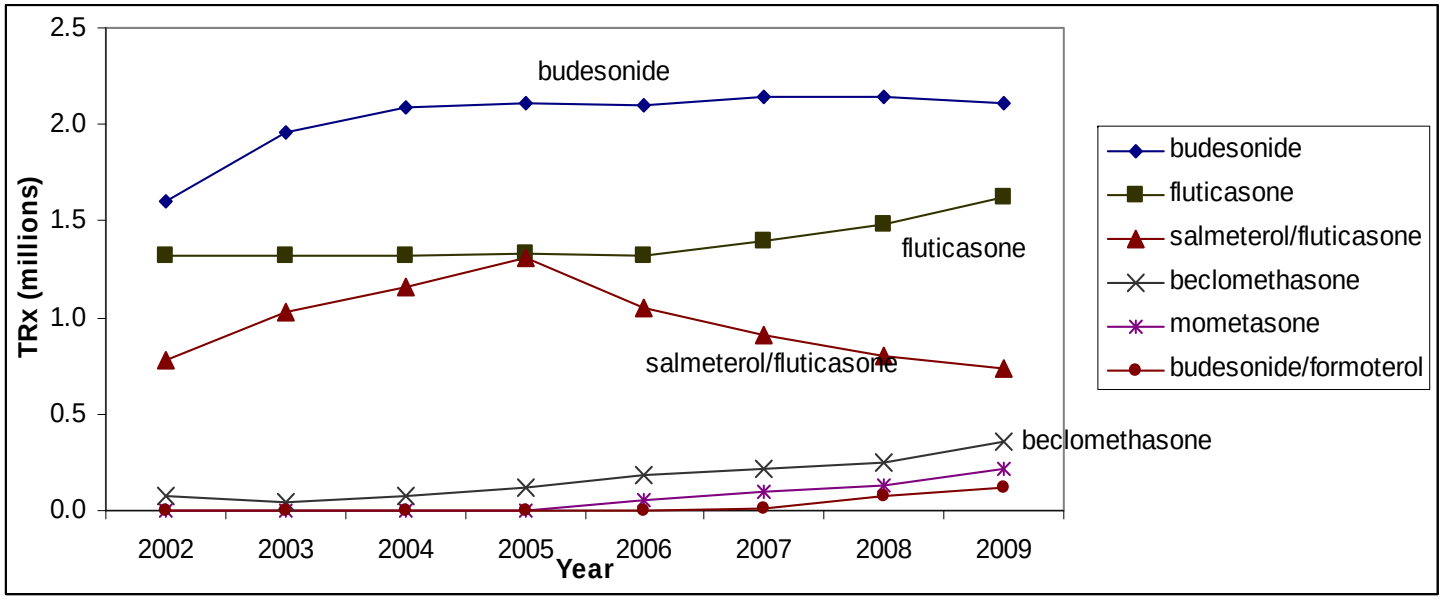
Source: SDI Vector One®: National. Years 2002-2009, extracted Feb2010. File: VONA 2010-207 ICS age, prod, strength1.xls

Table 7 Part 2: Total Dispensed Prescriptions for Selected Inhaled Corticosteroid Products by Patient Age (12+ years old) from U.S. Outpatient Retail Pharmacies, Years 2002-2009

Molecule	2002		2003		2004		2005		2006		2007		2008		2009		1/2002-12/2009	
Product	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*	TRxs	*Share*
Strength	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*	N	*%*
Age: 12+ years	19,479,132	*83.2%*	21,042,878	*82.3%*	21,537,199	*81.4%*	22,822,492	*81.5%*	23,592,955	*82.9%*	24,623,752	*83.4%*	25,727,551	*83.7%*	27,006,979	*83.6%*	185,832,938	*82.8%*
salmeterol/fluticasone	9,365,970	*48.1%*	12,852,070	*61.1%*	14,855,661	*69.0%*	16,807,254	*73.6%*	17,156,162	*72.7%*	17,557,355	*71.3%*	17,515,539	*68.1%*	17,332,342	*64.2%*	123,442,353	*66.4%*
Advair Diskus	9,365,970	*100.0%*	12,852,070	*100.0%*	14,855,661	*100.0%*	16,807,254	*100.0%*	17,136,187	*99.9%*	17,315,435	*98.6%*	17,127,061	*97.8%*	16,821,627	*97.1%*	122,281,265	*99.1%*
250/50MCG	4,422,390	*47.2%*	6,221,133	*48.4%*	7,576,077	*51.0%*	8,984,040	*53.5%*	9,525,701	*55.6%*	9,970,363	*57.6%*	10,146,492	*59.2%*	10,219,255	*60.8%*	67,065,451	*54.8%*
100/50MCG	3,370,291	*36.0%*	4,493,303	*35.0%*	4,812,825	*32.4%*	5,114,904	*30.4%*	4,781,847	*27.9%*	4,383,907	*25.3%*	3,969,560	*23.2%*	3,619,509	*21.5%*	34,546,146	*28.3%*
500/50MCG	1,573,289	*16.8%*	2,137,634	*16.6%*	2,466,759	*16.6%*	2,708,310	*16.1%*	2,828,639	*16.5%*	2,961,165	*17.1%*	3,011,009	*17.6%*	2,982,863	*17.7%*	20,669,668	*16.9%*
Advair HFA	--	--	--	--	--	--	--	--	19,975	*0.1%*	241,920	*1.4%*	388,478	*2.2%*	510,715	*2.9%*	1,161,088	*0.9%*
115/21MCG	--	--	--	--	--	--	--	--	13,420	*67.2%*	146,903	*60.7%*	218,408	*56.2%*	287,368	*56.3%*	666,099	*57.4%*
230/21MCG	--	--	--	--	--	--	--	--	2,220	*11.1%*	48,933	*20.2%*	99,433	*25.6%*	139,525	*27.3%*	290,111	*25.0%*
45/21MCG	--	--	--	--	--	--	--	--	4,335	*21.7%*	46,084	*19.0%*	70,637	*18.2%*	83,822	*16.4%*	204,878	*17.6%*
fluticasone	5,929,749	*30.4%*	4,979,449	*23.7%*	3,916,532	*18.2%*	3,358,482	*14.7%*	3,092,671	*13.1%*	2,971,354	*12.1%*	2,921,384	*11.4%*	3,092,986	*11.5%*	30,262,607	*16.3%*
Flovent HFA	--	--	--	--	--	--	2,047,973	*61.0%*	3,053,991	*98.7%*	2,962,139	*99.7%*	2,909,358	*99.6%*	3,059,886	*98.9%*	14,033,347	*46.4%*
110MCG	--	--	--	--	--	--	1,153,461	*56.3%*	1,700,197	*55.7%*	1,626,043	*54.9%*	1,599,960	*55.0%*	1,693,610	*55.3%*	7,773,271	*55.4%*
220MCG	--	--	--	--	--	--	562,331	*27.5%*	874,034	*28.6%*	876,475	*29.6%*	850,190	*29.2%*	876,748	*28.7%*	4,039,778	*28.8%*
44MCG	--	--	--	--	--	--	332,181	*16.2%*	479,760	*15.7%*	459,621	*15.5%*	459,208	*15.8%*	489,528	*16.0%*	2,220,298	*15.8%*
Flovent Diskus	--	--	--	--	--	--	--	--	--	--	1,917	*0.1%*	10,279	*0.4%*	32,340	*1.0%*	44,536	*0.1%*
50MCG	--	--	--	--	--	--	--	--	--	--	1,917	*100.0%*	10,260	*99.8%*	17,650	*54.6%*	29,827	*67.0%*
100MCG	--	--	--	--	--	--	--	--	--	--	--	--	7	*0.1%*	9,595	*29.7%*	9,602	*21.6%*
250MCG	--	--	--	--	--	--	--	--	--	--	--	--	12	*0.1%*	5,095	*15.8%*	5,107	*11.5%*
All Others	5,929,749	*100.0%*	4,979,449	*100.0%*	3,916,532	*100.0%*	1,310,509	*39.0%*	38,680	*1.3%*	7,298	*0.2%*	1,747	*0.1%*	760	*0.0%*	16,184,724	*53.5%*
budesonide/formoterol	--	--	--	--	--	--	--	--	--	--	174,250	*0.7%*	1,288,668	*5.0%*	2,469,753	*9.1%*	3,932,671	*2.1%*
Symbicort	--	--	--	--	--	--	--	--	--	--	174,250	*100.0%*	1,288,668	*100.0%*	2,469,753	*100.0%*	3,932,671	*100.0%*
160/4.5MCG	--	--	--	--	--	--	--	--	--	--	124,012	*71.2%*	946,484	*73.4%*	1,889,686	*76.5%*	2,960,182	*75.3%*
80/4.5MCG	--	--	--	--	--	--	--	--	--	--	50,238	*28.8%*	342,184	*26.6%*	580,067	*23.5%*	972,489	*24.7%*
budesonide	992,733	*5.1%*	1,052,392	*5.0%*	1,061,419	*4.9%*	1,030,392	*4.5%*	1,047,138	*4.4%*	1,089,665	*4.4%*	1,185,053	*4.6%*	1,309,845	*4.9%*	8,768,637	*4.7%*
Pulmicort Flexhaler	--	--	--	--	--	--	--	--	--	--	280,705	*25.8%*	640,725	*54.1%*	638,771	*48.8%*	1,560,201	*17.8%*
180 MCG	--	--	--	--	--	--	--	--	--	--	258,895	*92.2%*	576,917	*90.0%*	558,669	*87.5%*	1,394,481	*89.4%*
90MCG	--	--	--	--	--	--	--	--	--	--	21,810	*7.8%*	63,808	*10.0%*	80,102	*12.5%*	165,720	*10.6%*
Pulmicort Respules	166,309	*16.8%*	273,784	*26.0%*	368,778	*34.7%*	390,447	*37.9%*	413,630	*39.5%*	482,444	*44.3%*	517,516	*43.7%*	497,742	*38.0%*	3,110,650	*35.5%*
0.5MG	127,053	*76.4%*	217,749	*79.5%*	300,138	*81.4%*	323,728	*82.9%*	347,383	*84.0%*	402,745	*83.5%*	419,274	*81.0%*	385,551	*77.5%*	2,523,621	*81.1%*
0.25MG	39,256	*23.6%*	56,035	*20.5%*	68,640	*18.6%*	66,719	*17.1%*	66,247	*16.0%*	77,660	*16.1%*	73,453	*14.2%*	67,073	*13.5%*	515,083	*16.6%*
1MG	--	--	--	--	--	--	--	--	--	--	2,039	*0.4%*	24,789	*4.8%*	45,118	*9.1%*	71,946	*2.3%*
Budesonide	--	--	--	--	--	--	--	--	--	--	--	--	22,260	*1.9%*	172,769	*13.2%*	195,029	*2.2%*
0.5MG	--	--	--	--	--	--	--	--	--	--	--	--	19,314	*86.8%*	150,828	*87.3%*	170,142	*87.2%*
0.25MG	--	--	--	--	--	--	--	--	--	--	--	--	2,946	*13.2%*	21,941	*12.7%*	24,887	*12.8%*
All Others	826,424	*83.2%*	778,608	*74.0%*	692,641	*65.3%*	639,945	*62.1%*	633,508	*60.5%*	326,516	*30.0%*	4,552	*0.4%*	563	*0.0%*	3,902,757	*44.5%*
mometasone	--	--	--	--	--	--	51,448	*0.2%*	724,874	*3.1%*	1,314,380	*5.3%*	1,350,449	*5.2%*	1,280,734	*4.7%*	4,721,885	*2.5%*
Asmanex	--	--	--	--	--	--	51,448	*100.0%*	724,874	*100.0%*	1,314,380	*100.0%*	1,350,449	*100.0%*	1,280,734	*100.0%*	4,721,885	*100.0%*
220MCG	--	--	--	--	--	--	51,448	*100.0%*	724,874	*100.0%*	1,314,380	*100.0%*	1,339,552	*99.2%*	1,229,510	*96.0%*	4,659,764	*98.7%*
110MCG	--	--	--	--	--	--	--	--	--	--	--	--	10,897	*0.8%*	51,224	*4.0%*	62,121	*1.3%*
beclomethasone	785,596	*4.0%*	292,567	*1.4%*	356,091	*1.7%*	487,454	*2.1%*	654,841	*2.8%*	733,040	*3.0%*	804,249	*3.1%*	1,007,460	*3.7%*	5,121,298	*2.8%*
Qvar	118,276	*15.1%*	260,787	*89.1%*	355,533	*99.8%*	487,274	*100.0%*	654,744	*100.0%*	732,987	*100.0%*	804,226	*100.0%*	1,007,444	*100.0%*	4,421,271	*86.3%*
80MCG	74,729	*63.2%*	150,469	*57.7%*	225,642	*63.5%*	324,901	*66.7%*	443,322	*67.7%*	500,004	*68.2%*	549,349	*68.3%*	694,518	*68.9%*	2,962,934	*67.0%*
40MCG	43,547	*36.8%*	110,318	*42.3%*	129,891	*36.5%*	162,373	*33.3%*	211,422	*32.3%*	232,983	*31.8%*	254,877	*31.7%*	312,926	*31.1%*	1,458,337	*33.0%*
All Others	667,320	*84.9%*	31,780	*10.9%*	558	*0.2%*	180	*0.0%*	97	*0.0%*	53	*0.0%*	23	*0.0%*	16	*0.0%*	700,027	*13.7%*
triamcinolone	1,840,728	*9.4%*	1,423,588	*6.8%*	1,019,759	*4.7%*	841,930	*3.7%*	731,270	*3.1%*	635,937	*2.6%*	543,557	*2.1%*	351,775	*1.3%*	7,388,544	*4.0%*
Azmacort	1,840,728	*100.0%*	1,423,588	*100.0%*	1,019,759	*100.0%*	841,930	*100.0%*	731,270	*100.0%*	635,937	*100.0%*	543,557	*100.0%*	351,775	*100.0%*	7,388,544	*100.0%*
75MCG	--	--	--	--	--	--	--	--	--	--	--	--	46,822	*8.6%*	310,300	*88.2%*	357,122	*4.8%*
100MCG	1,840,728	*100.0%*	1,423,588	*100.0%*	1,019,759	*100.0%*	841,930	*100.0%*	731,270	*100.0%*	635,937	*100.0%*	496,735	*91.4%*	41,475	*11.8%*	7,031,422	*95.2%*
All Others	564,356	*2.9%*	442,812	*2.1%*	327,737	*1.5%*	245,532	*1.1%*	185,999	*0.8%*	147,771	*0.6%*	118,652	*0.5%*	162,084	*0.6%*	2,194,943	*1.2%*
Unspecified Age	90,177	*0.4%*	95,869	*0.4%*	236,694	*0.9%*	281,863	*1.0%*	141,037	*0.5%*	103,753	*0.4%*	93,996	*0.3%*	95,966	*0.3%*	1,139,355	*0.5%*

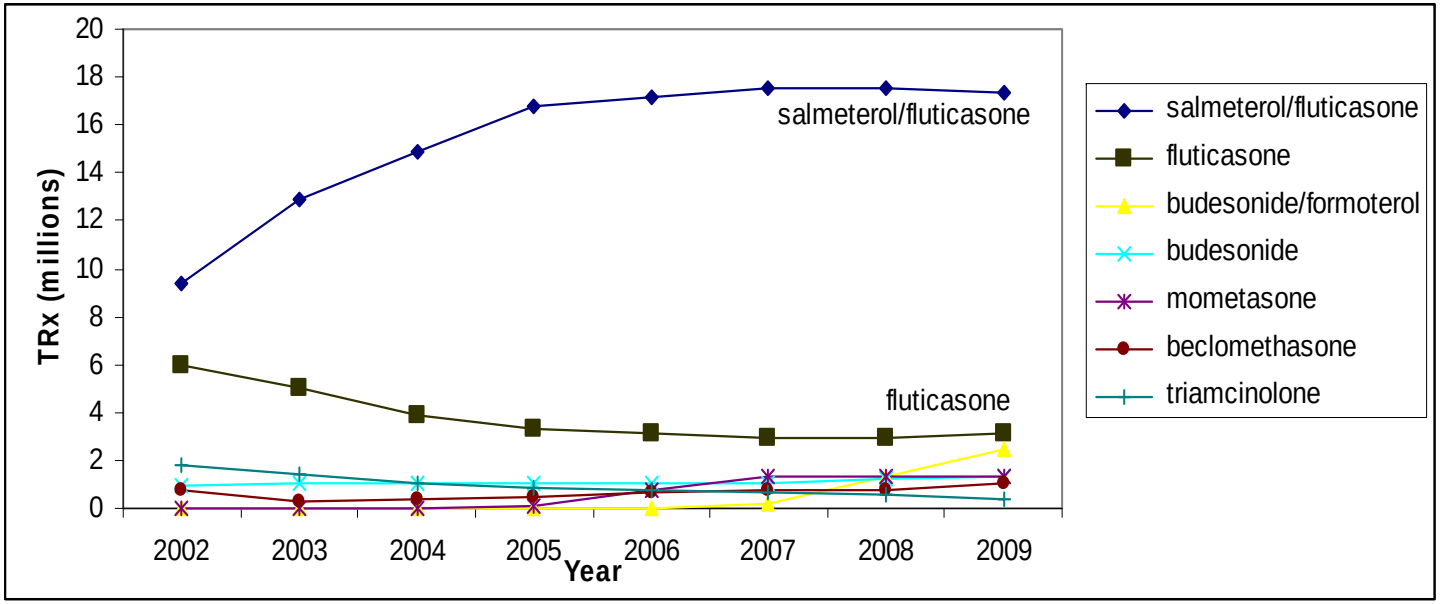
Source: SDI Vector One®: National. Years 2002-2009, extracted Feb2010. File: VONA 2010-207 ICS age, prod, strength1.xls

Figure 3: Total Dispensed Prescriptions for Selected Inhaled Corticosteroid Products in the Pediatric Population (0-11 years), Years 2002-2009



Source: SDI Vector One®: National. Years 2002-2009, extracted Feb2010. File: VONA 2010-207 ICS age, prod, strength1.xls

Figure 4: Total Dispensed Prescriptions for Selected Inhaled Corticosteroid Products in the 12+ Years Patient Population, Years 2002-2009



Source: SDI Vector One®: National. Years 2002-2009, extracted Feb2010. File: VONA 2010-207 ICS age, prod, strength1.xls

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
SAFETY-351	ORIG-1	NO FIRM	SALMETEROL XINAFOATE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GRACE P CHAI
02/18/2010

LAURA A GOVERNALE
02/18/2010
Drug use data cleared for public release.